



## Ocular Irritation Potential of Cosmetic Products: Comparative Study of *In Vitro* and *In Vivo* Tests

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**SUMMARY.** The evaluation of the eye irritation potential of cosmetic products is essential to assure their safety. The red blood cells hemolytic assay (RBC) was used to estimate potential irritation. Thirteen cosmetic formulations were evaluated using an *in vitro* assay according to INVITOX protocol n° 37 and the Draize's test was employed as an *in vivo* assay. The maximum average score (MAS) and the effective concentration 50 of haemolysis and the denaturation index ratio (H<sub>50</sub>/DI) values were used as parameters for *in vivo* and *in vitro* assays, respectively. The Pearson's and Spearman's correlation coefficients were 0.6479 and 0.6324, respectively. The concordance between the H50/DI ratio and MAS was 76.9% while the RBC assay was suitable to predict the irritation potential with a sensitivity and specificity values of 77.7 and 75.0%, respectively. The RBC assay has proved to be an inexpensive and rapid test and it does not require the use of sophisticated equipment, providing reliable results with good reproducibility and showing a good correlation between the parameters estimated *in vitro* and the maximum average scores obtained *in vivo*. In this context, this study offers more evidence to contribute to the validation of this method.

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**KEY WORDS:** Cosmetic products, Draize's test, Ocular irritation, Red blood cell assay.

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